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Dental Institute, University of Zurich
Clinic of Preventive Dentistry, Periodontology and Cariology
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# TELEMETRIC EVALUATION OF D-TAGATOSE PROVIDED BY MD FOODS INGREDIENTS AMBA, DK-8260 VIBY J, DENMARK WITH REGARD TO THE PRODUCT'S QUALIFICATION AS BEING "SAFE FOR TEETH"

# INTRODUCTION

Numerous laboratory and clinical tests have been suggested for the evaluation of the cariogenicity of diet [1, 2]. Caries results from a disturbance of the equilibrium of enamel hydroxyapatite and the calcium and phosphate ion concentrations of dental plaque. The formation of organic acids in dental plaque after the exposure to fermentable dietary carbohydrates and the corresponding decreases of plaque-pH are generally agreed to be closely associated with the initiation of dental decay. Plaque acidogenicity of a food item, i.e. its potential to cause low pH-values in dental plaque due to glycolytic acid formation, consequently is an important factor in caries etiology.

Today intraoral plaque-pH-telemetry, first published in 1965 and 1966 [3, 4], is still the only in vivo method to quickly and accurately assess the hydronium ion concentration under an undisturbed layer of plaque at the level of the enamel surface of the teeth. The pH of interdental plaque can be recorded continuously during and following the intake, chewing and sucking of foods, beverages, snacks or medicines. The measurements do not disturb the habitual consumption nor the normal diffusion of substrates into the interdental areas and plaque. The neutralizing effect of salivary buffers as well as an eventual alcalinization of acidified plaque by buffers added to manufactured products are adequately assessed in a natural environment. Reversible pH-drops of oral fluid and of dental plaque provoked by acids contained in foods and drinks can also be registered during the measurements. Dietary acids are often added to processed foods for several purposes such as flavour enhancement and modification, food preservation, pectine gelation, inhibition of enzymatic browning, etc. Such acids may lead to dental erosion. Erosion is a localized, chronic, painless loss of dental hard tissue etched away by acid from the tooth surface without involving bacteria. Should the plaque-pH be depressed by dietary acids during the consumption of a product tested, an additional evaluation is performed to assess the degree of the potentially erosive acid attack in $\mu$mol $H^+$ x min/L. If, irrespective of the substitution of fermentable carbohydrates in the product, a product is classified as potentially leading to dental erosion based on the above mentioned evaluation (>40 $\mu$mol $H^+$ x min/L), then this product can no more be labelled "safe for teeth".

Plaque-pH-telemetry as such, however, cannot be used for an immediate prediction of the cariogenicity of dietary components because the individual frequency of consumption is not known. In spite of this uncertainity in predicting high cariogenicity or even different degrees of cariogenicity this method is a valid and feasible way to predict no or very low cariogenicity [5]. Frequency of consumption can be disregarded if in vivo intraplaque acid formation does not produce pH-drops below a value of 5.7. Telemetrically recorded plaque-pH-values after the ingestion of a substance at or above this arbitrary limit of 5.7 can be regarded as a criterion of a low cariogenic potential of the tested food.

Intraoral telemetry was reviewed and the method described in detail in 1982 and 1983 [6,7]. Its reproducibility was assessed in longterm retrospective studies comparing the findings after administration of standard sucrose rinses in volunteers over periods of 2 to 5 years. The consistency of the results proved to be excellent [8, 9, 10]. A comparison of pH-telemetric findings after equal carbohydrate exposures in children, adolescents and adults supported the extrapolation of results of adult volunteers to the average consumer [11]. The aim of intraoral plaque-pH-telemetry is to identify foods and snacks of low cariogenic potential. Although it is realistically impossible to eliminate sucrose from the diet, it is possible to reduce the frequency and duration of the acid challenge by providing non- or hypo-acidogenic analogues for the most frequently (ab)used snack-foods.

In 1969 the Swiss Office of Health (Bundesamt für Gesundheitswesen, BAG) introduced legislation for the labelling of sweet confections with regard to dental health: Confectioneries labelled "safe for teeth" (German: "zahnschonend" or "zahnfreundlich") are products that have proved under in vivo conditions in man not to depress the pH of interdental plaque below 5.7 by bacterial fermentation neither during consumption nor up to 30 minutes later (Swiss Food Ordinance (Lebensmittelverordnung LMV), Art. No. 176, Paragraph 2). This critical limit is only valid when plaque-pH is assessed telemetrically in vivo.

In Switzerland manufacturers are allowed to advertize their products as "safe for teeth" after submitting convincing pH-telemetric tests to the Swiss Office of Health. Labelling a product as "non-cariogenic" (German: "nicht kariogen") is only allowed when based on a longterm clinical caries incidence study. The Swiss regulations for product labelling concerning dental health are an efficient means to allow consumers to make informed choices when they select foods, snacks and beverages. This is one of the basic tenants of dietary counselling in preventive dentistry.

## MATERIALS AND METHODS

In October 1996, the Bioelectronic Unit of the Clinic of Preventive Dentistry, Periodontology and Cariology of the University Dental Institute of Zurich, received a sample of D-Tagatose from MD Foods Ingredients amba, with the request to perform telemetric tests of the product's qualification as being "safe for teeth" according to the regulations by the Swiss Federal Office of Health.

The specification of the product called **D-Tagatose**, a 6-carbon sugar, was disclosed to the investigator as well as a summary of safety tests performed elsewhere and it was confirmed that the product is approved for food use in Australia, New Zealand and Hong Kong.

The tests were performed by PD Dr.T.Imfeld, DDS, MBA, Mrs. J. Jenss, assistant, and Mr. T.Reich, bioengineer. Six persons in good general health served as test subjects. They had all previously participated in similar studies and their response to certain control procedures is well known. Average plaque-pH-values in response to 10% sucrose rinses recorded during the course of several years in these volunteers are stored in the computer data bank for comparison with the positive (sucrose) controls used in the study.
For interdental plaque-pH telemetry each subject had a mandibular telemetric prosthesis incorporating a miniaturized glass pH-electrode so placed as to directly oppose the interproximal area of an adjacent abutment tooth. These test prostheses with clean pH-electrodes were inserted and the subjects were asked not to alter their eating habits. With the single exception of water rinses, they were bound to refrain from all oral hygiene measures. The prostheses were not removed during the test period, thus allowing an undisturbed growth of interdental plaque over the tips of the interdentally orientated electrodes. The pH-recordings were performed according to the method described by Imfeld [6, 7]. Sucrose rinses 0.3 mol/L (10%) were used as positive controls.

## EXPERIMENTAL

| Test Pattern I (Figs. 1 to 6) | min |
|---|---|
| - Paraffin chewing | 3 |
| - Resting period | 4 |
| - Control period | 15 |
| - 15 ml 10% aqueous Tagatose rinse | 2 |
| - Control period | 30 |
| - Water rinse | 2 |
| - Paraffin chewing | 3 |
| - Resting period | 4 |
| - 15 ml 0.3 mol/L sucrose rinse | 2 |
| - Control period | 30 |
| - Water rinse | 2 |
| - Paraffin chewing | 3 |
| - Resting period | 4 |

## RESULTS

The pH-telemetric results are presented in Figs. 1 to 6 and summarized in Table I. The pH-values registered following the chewing of neutral paraffin (PC) coincide with those found in earlier tests with the same volunteers and plaque ages. They suggest physiological oral conditions in the test subjects. The pH-decreases occurring subsequently to the 0.3 mol/L (10%) sucrose rinses used as positive control gave evidence of an accurate functioning of the pH-telemetric equipment and of plaque metabolism.

The results in Figs. 1 to 6 clearly show that there was no critical (i.e. below pH 5.7) decrease in the pH of interdental plaque due to bacterial fermentation of Tagatose neither during the rinsing periods nor during the 30 minute periods following the consumption of the tested Tagatose solutions. After the consumption of sucrose (sucrose rinse), plaque-pH always fell well below the critical pH-value (5.7) due to the glycolytic production of bacterial acids.

D-Tagatose has earlier been described as being hypoacidogenic in the oral cavity because it is only very slowly fermented by oral microorganisms[7].

## CONCLUSIONS

According to the regulations by the Swiss Federal Office of Health (Art. 176, § 2, LMV), a product is "safe for teeth" (German: "zahnschonend" or "zahnfreundlich") if it can be shown under in vivo-conditions in man that the pH of interdental plaque does not decrease below 5.7 because of bacterial glycolysis of fermentable substrate neither during the product's consumption nor up to 30 minutes subsequently. This study shows that the tested hexose D-Tagatose provided by MD Foods Ingredients amba, DK-8260 Viby J, does fulfill these requirements. The product might therefore be useful for the production of sweet confectionery to be registered as "safe for teeth". The use of the pictograph of the Toothfriendly Sweets International Association ("Aktion Zahnfreundlich International") is regulated by the secretariate of this Association and such labelling is only permitted after registration with the Association if the product is "safe for teeth".

PD Dr.T.Imfeld, DDS, MBA

Zurich, November 1996
G13/candy-b

# Legends to Figures

Figs. 1 to 6

Telemetrically recorded pH of interdental plaque in different volunteers during and for 30 min after a 2 min rinse of a 10% aqueous solution of D-Tagatose. Two-minute 0.3 mol/L (10%) sucrose rinses were administered as positive controls. (PC) = Paraffin chewing. (id) = age of interdental plaque (i) in days (d).

## LITERATURE


1. Proceedings "Methods of Caries Prediction". Eds. Bibby and Shern. Sp. Supp. Microbiology Abstracts, 1978.

2. Scientific Consensus Conference on Methods for Assessment of the Cariogenic Potential of Foods, San Antonio, Texas, Nov. 17-21, 1985. J Dent Res 65 (Spec Iss), 1473-1543, 1986.

3. Graf, H., Mühlemann, H.R.: Glass electrode telemetry of pH-changes of interdental human plaque. J Dent Res (Abstract) 44, 1039, 1965.

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5. Mühlemann, H.R.: Sugar substitutes and plaque-pH-telemetry in caries prevention. J Clin Periodontol 6, Extra Issue 7, 47, 1979.

6. Imfeld, T.: Interdental Plaque-pH-Telemetry. In "Surface and Colloid Phenomena in the Oral Cavity: Methodological Aspects." Proceedings of a workshop on saliva-dental plaque and enamel surface interactions, Eds. Frank and Leach, IRL Press Ltd., London, pp. 143 - 156, 1982.

7. Imfeld, T.: Identification of low caries risk dietary components. Monographs in Oral Science, Vol. 11, S. Karger, Basel, 1983.

8 Imfeld, T.: In vivo assessment of plaque acid production, a long-term retrospective study. In: "Health and Sugar Substitutes". Proceedings ERGOB Conf., Geneva 1978, S. Karger, Basel, pp. 218 - 223, 1979.

9. Firestone, A.R., Imfeld, T. and Schiffer, S.: Reproducibility of in vivo interdental plaque-pH measurements in humans following a sucrose rinse. Caries Res 19, 189 - 190, 1985.

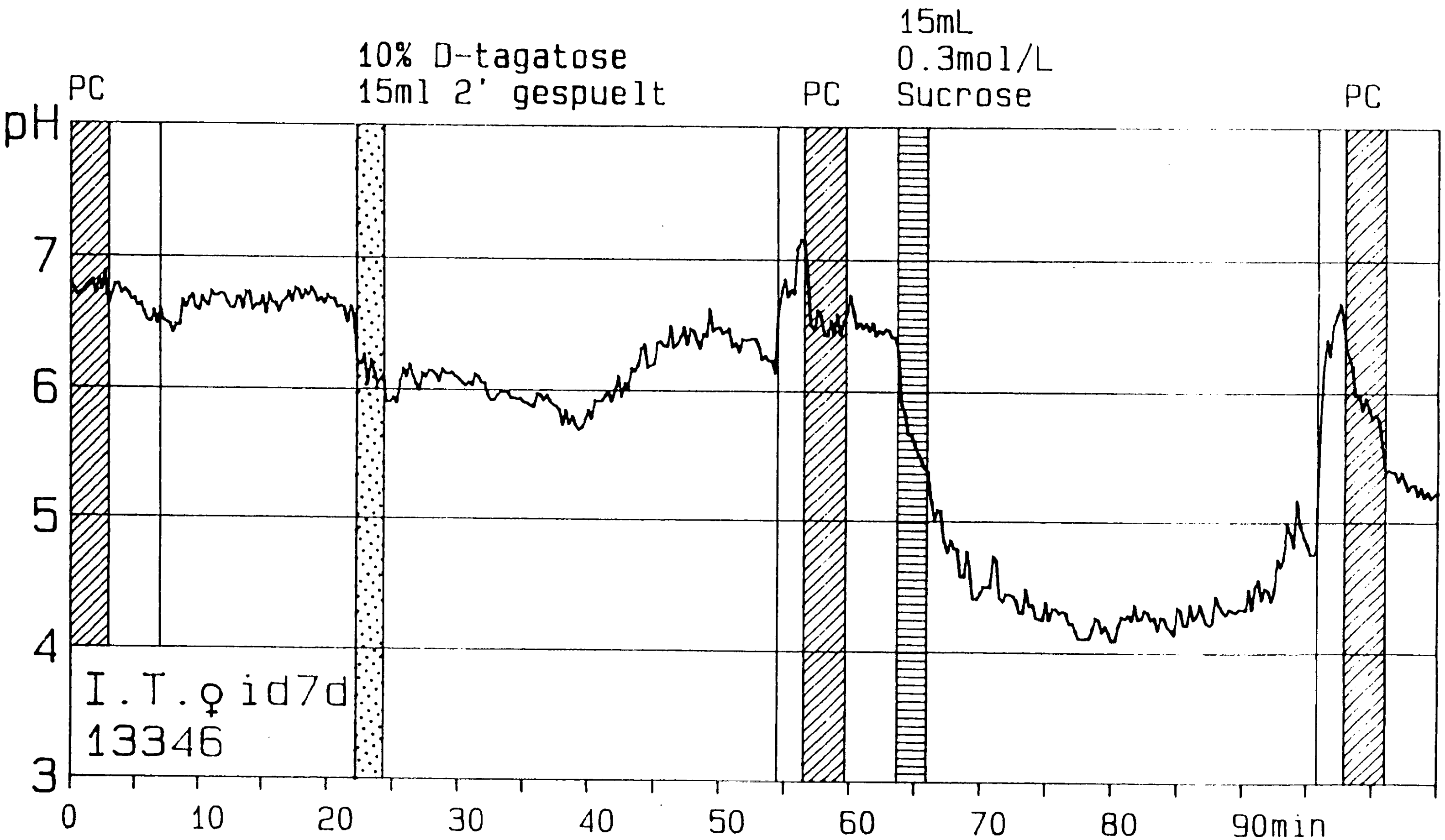
10. Firestone, A.R., Imfeld, T., Schiffer, S., Lutz, F.: Measurement of interdental plaque pH in humans with an indwelling glass pH electrode following a sucrose rinse: A long-term retrospective study. Caries Res 21, 555 - 558, 1987.

11. Imfeld, T., Lutz, F.: Intraplaque acid formation assessed in vivo in children and young adults. Pediatric Dentistry 2, 87-93, 1980.

Table I

Influence of different test patterns on the telemetrically measured pH of interdental plaque. The pH-values listed are the lowest values found during the respective control periods of the recording sessions.

| Test Pattern | | | I. | | | |
|---|---|---|---|---|---|---|
| Measurements | | | 6 | | | |
| Figure | 1 | 2 | 3 | 4 | 5 | 6 |
| Age of Plaque (days) | 7 | 3 | 6 | 4 | 5 | 4 |
| pH initial Paraffin | 6.80 | 6.70 | 7.10 | 7.15 | 6.85 | 6.95 |
| pH 10% D-Tagatose | 5.70 | 5.75 | 6.30 | 6.20 | 6.25 | 5.95 |
| pH 0.3 mol/L sucrose | 4.10 | 4.35 | 4.60 | 4.20 | 4.50 | 4.45 |
| pH final Paraffin | 5.35 | 5.80 | 6.60 | 6.00 | 6.60 | 6.15 |



PC
10% D-tagatose
15ml 2' gespuelt
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
I.T.♀id7d
13346
0
10
20
30
40
50
60
70
80
90min


Fig. 1

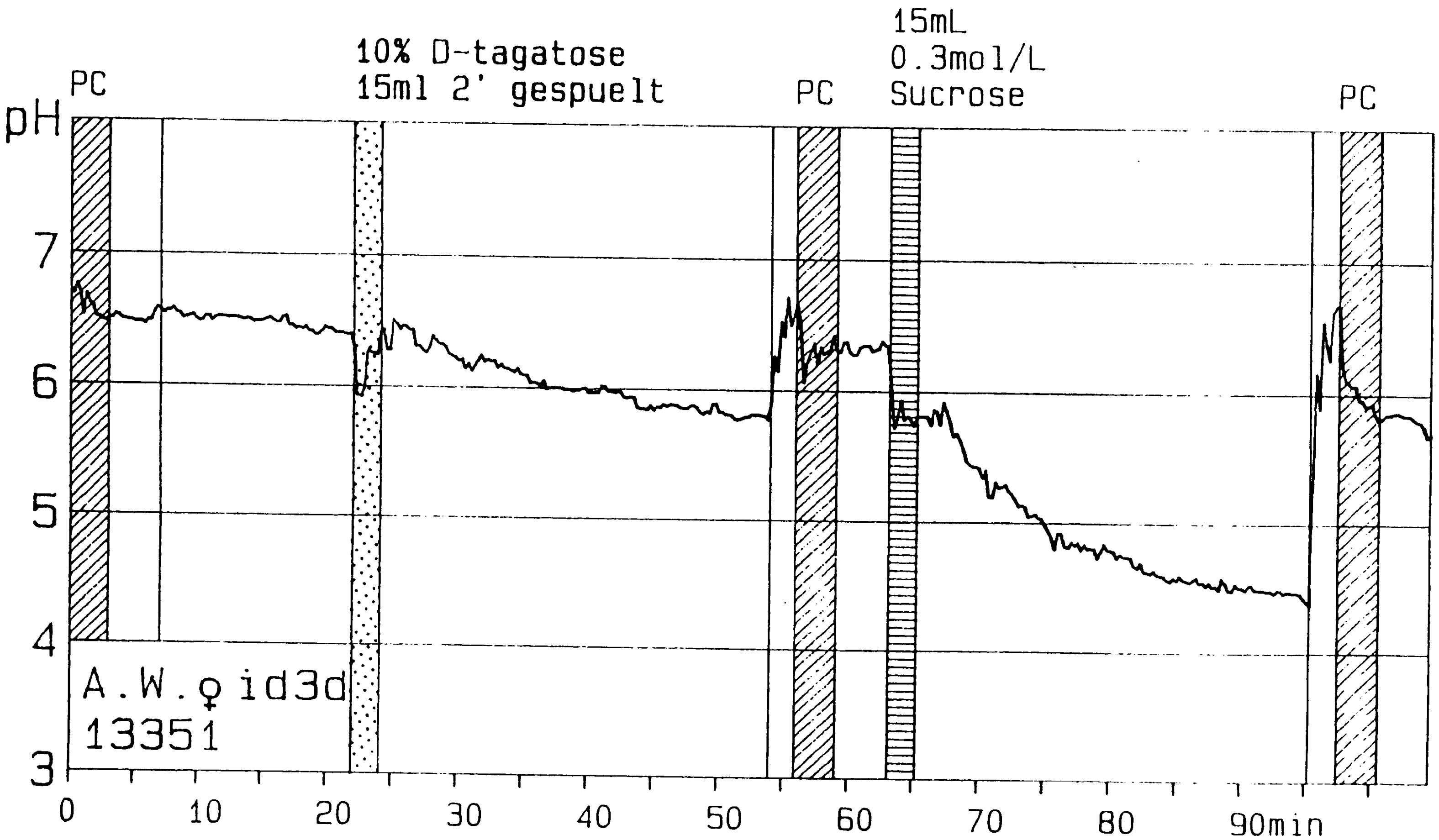

PC
10% D-tagatose
15ml 2' gespuelt
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
A.W.♀ id3d
13351
0
10
20
30
40
50
60
70
80
90min

Fig. 2

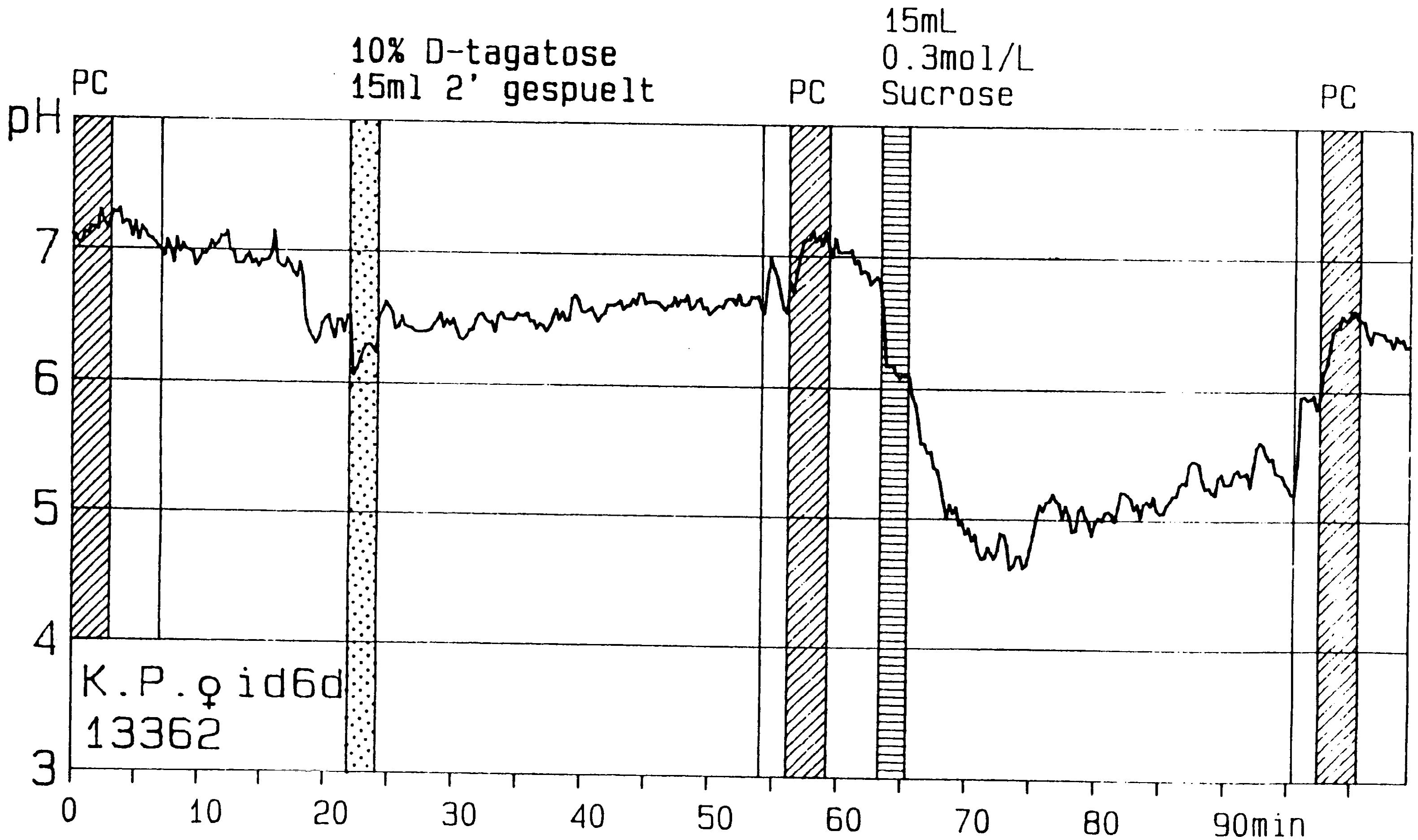

PC
10% D-tagatose
15ml 2' gespuelt
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
K.P.♀ id6d
13362
0
10
20
30
40
50
60
70
80
90min

Fig. 3

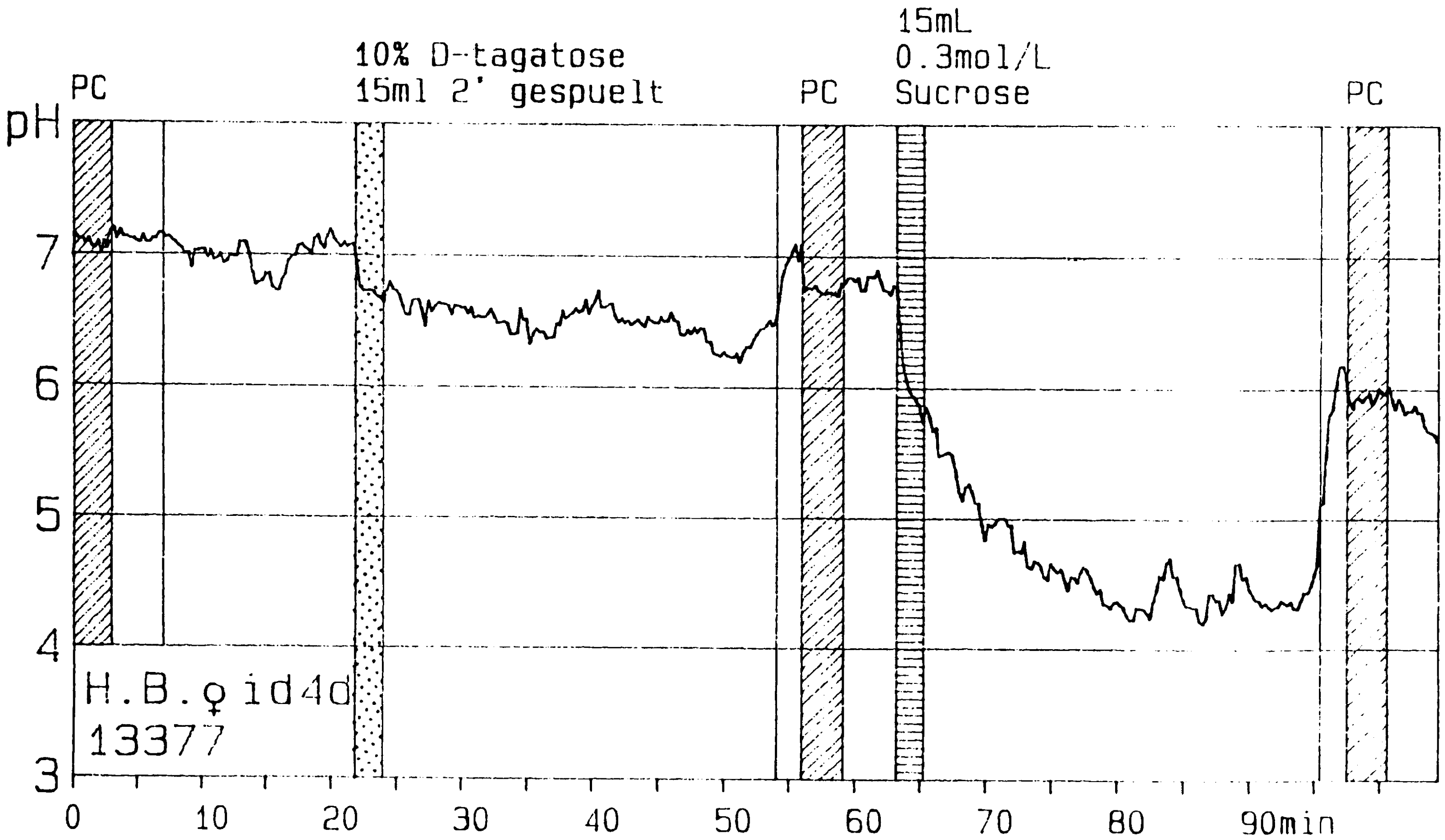
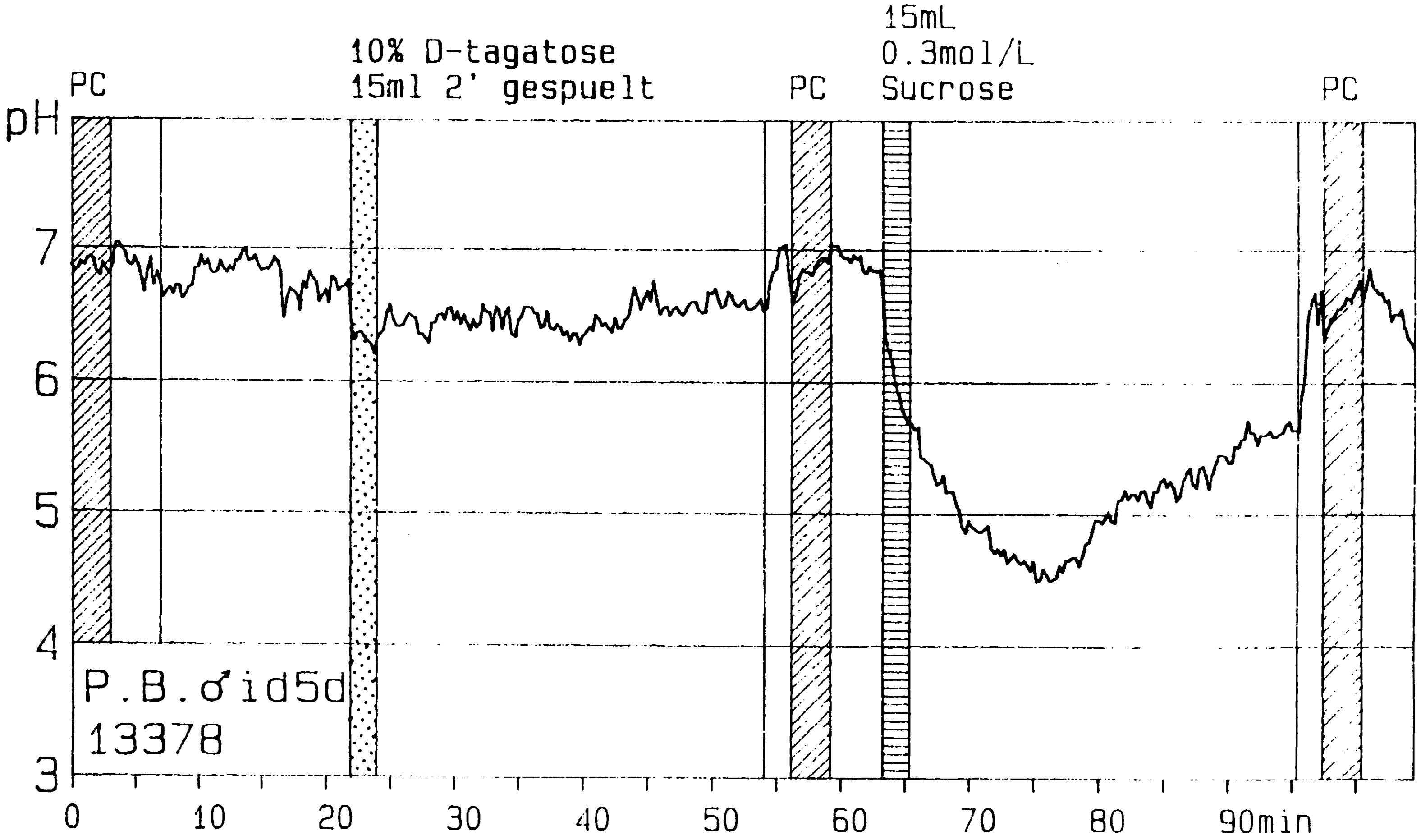
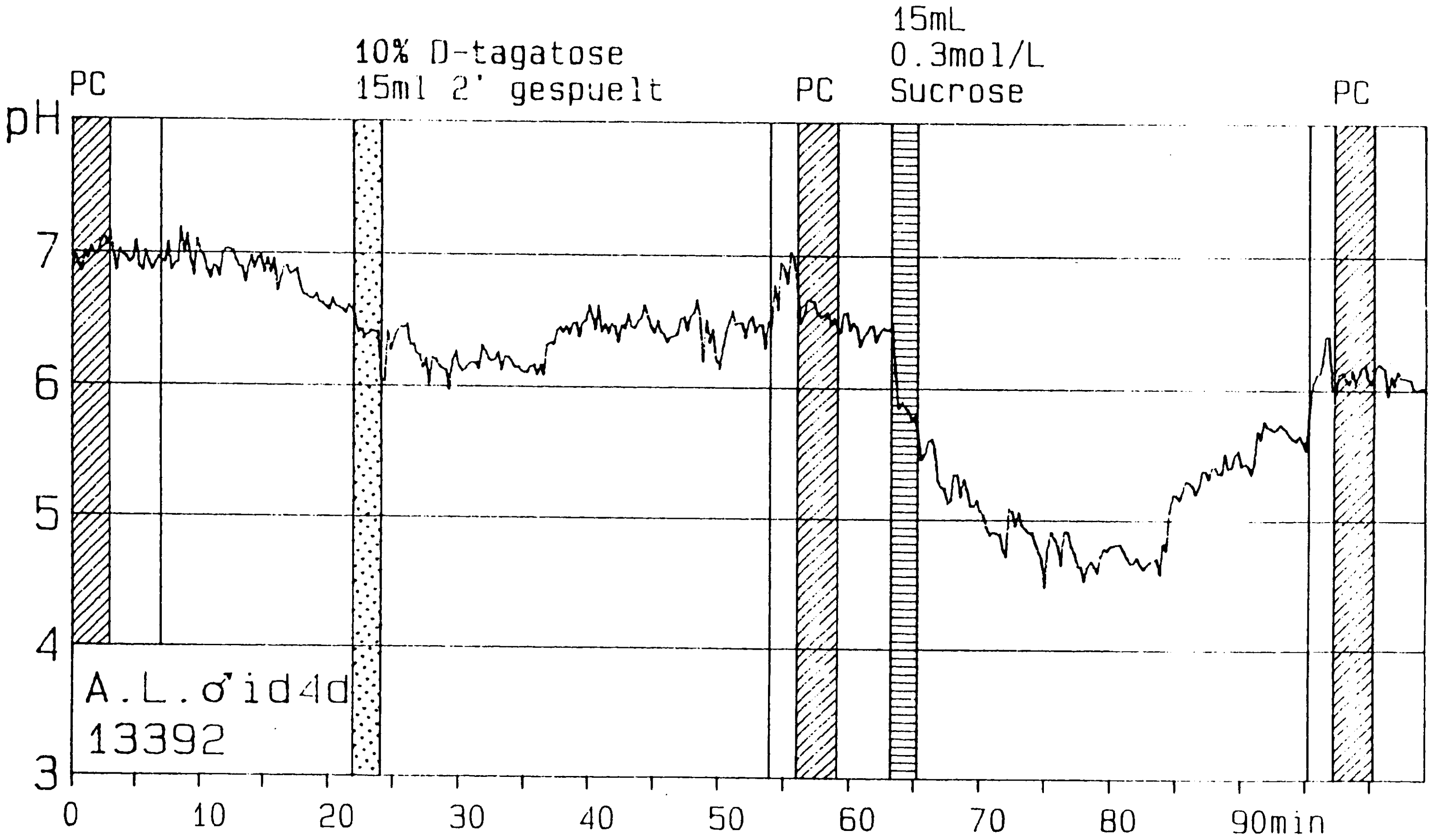

PC
10% D-tagatose
15ml 2' gespuelt
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
H.B.♀ id4d
13377
0
10
20
30
40
50
60
70
80
90min

Fig. 4



PC
10% D-tagatose
15ml 2' gespuelt
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
P.B.♂id5d
13378
0
10
20
30
40
50
60
70
80
90min


Fig. 5



PC
10% D-tagatose
15ml 2' gespuelt
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
A.L.♂id4d
13392
0
10
20
30
40
50
60
70
80
90min


Fig. 6

1998

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Clinic of Preventive Dentistry, Periodontology and Cariology
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# INTRODUCTION

Numerous laboratory and clinical tests have been suggested for the evaluation of the cariogenicity of diet [1, 2]. Caries results from a disturbance of the equilibrium of enamel hydroxyapatite and the calcium and phosphate ion concentrations of dental plaque. The formation of organic acids in dental plaque after the exposure to fermentable dietary carbohydrates and the corresponding decreases of plaque-pH are generally agreed to be closely associated with the initiation of dental decay. Plaque acidogenicity of a food item, i.e. its potential to cause low pH-values in dental plaque due to glycolytic acid formation, consequently is an important factor in caries etiology.

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Intraoral telemetry was reviewed and the method described in detail in 1982 and 1983 [6,7]. Its reproducibility was assessed in longterm retrospective studies comparing the findings after administration of standard sucrose rinses in volunteers over periods of 2 to 5 years. The consistency of the results proved to be excellent [8, 9, 10]. A comparison of pH-telemetric findings after equal carbohydrate exposures in children, adolescents and adults supported the extrapolation of results of adult volunteers to the average consumer [11]. The aim of intraoral plaque-pH-telemetry is to identify foods and snacks of low cariogenic potential. Although it is realistically impossible to eliminate sucrose from the diet, it is possible to reduce the frequency and duration of the acid challenge by providing non- or hypo-acidogenic analogues for the most frequently (ab)used snack-foods.

In 1969 the Swiss Office of Health (Bundesamt für Gesundheitswesen, BAG) introduced legislation for the labelling of sweet confections with regard to dental health: Confectioneries labelled "safe for teeth" (German: "zahnschonend" or "zahnfreundlich") are products that have proved under in vivo conditions in man not to depress the pH of interdental plaque below 5.7 by bacterial fermentation neither during consumption nor up to 30 minutes later (Swiss Food Ordinance (Lebensmittelverordnung LMV), Art. No. 176, Paragraph 2). This critical limit is only valid when plaque-pH is assessed telemetrically in vivo.

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## MATERIALS AND METHODS

In October 1996, the Bioelectronic Unit of the Clinic of Preventive Dentistry, Periodontology and Cariology of the University Dental Institute of Zurich, received a sample of D-Tagatose from MD Foods Ingredients amba, with the request to perform telemetric tests of the product's qualification as being "safe for teeth" according to the regulations by the Swiss Federal Office of Health.

The specification of the product called **D-Tagatose**, a 6-carbon sugar, was disclosed to the investigator as well as a summary of safety tests performed elsewhere and it was confirmed that the product is approved for food use in Australia, New Zealand and Hong Kong.

A 10% aqueous solution of D-Tagatose proved safe for teeth and the respective report was sent to MD Foods Ingredients amba in November 1996.

As D-Tagatose is a sugar and not a sugaralcohol, however, the question came up whether it would eventually be fermented by plaque bacteria provided they were given a chance to adapt to the product during a period of more frequent exposure. A pilot plaque adaptation study was consequently planned and proposed to MD Food Ingredinets amba (letter from Dr. A. Bär, Bioresco Ltd., dated August 18, 1997).

In order to assess the effect of frequent exposure to D-Tagatose on intraplaque acid production it was proposed to measure intraplaque pH in the same six volunteers that had been involved in the above mentioned study in 1996. These plaque pH recordings were planned to be performed in every volunteer at the same age of plaque as in the original study but this time after exposure to D-Tagatose during plaque growth.

The tests were performed by PD Dr.T.Imfeld, DDS, MBA, Mrs. J. Jenss, assistant, and Mr. T.Reich, bioengineer. Six persons in good general health served as test subjects. They had all previously participated in similar studies and their response to certain control procedures is well known. Average plaque-pH-values in response to 10% sucrose rinses recorded during the course of several years in these volunteers are stored in the computer data bank for comparison with the positive (sucrose) controls used in the study.

For interdental plaque-pH telemetry each subject had a mandibular telemetric prosthesis incorporating a miniaturized glass pH-electrode so placed as to directly oppose the interproximal area of an adjacent abutment tooth. These test prostheses with clean pH-electrodes were inserted and the subjects were asked not to alter their eating habits. With the single exception of water rinses, they were bound to refrain from all oral hygiene measures. The prostheses were not removed during the test period, thus allowing an undisturbed growth of interdental plaque over the tips of the interdentally orientated electrodes. During the individual periods of plaque accumulation, the volunteers were rinsing with D-Tagatose solutions. In detail the volunteers rinsed 5 times per day. Each of the 5 rinsing applications consisted of 2 times 2 minutes of rinsing with 15 ml of 10% aqueous solution of D-Tagatose each in a row. The pH-recordings were performed according to the method described by Imfeld [6, 7]. Sucrose rinses 0.3 mol/L (10%) were used as positive controls.

## EXPERIMENTAL

| Test Pattern I (Figs. 1 to 6) | min |
|---|---|
| - Paraffin chewing | 3 |
| - Resting period | 4 |
| - Control period | 15 |
| - 15 ml 10% aqueous Tagatose rinse | 2 |
| - Control period | 30 |
| - Water rinse | 2 |
| - Paraffin chewing | 3 |
| - Resting period | 4 |
| - 15 ml 0.3 mol/L sucrose rinse | 2 |
| - Control period | 30 |
| - Water rinse | 2 |
| - Paraffin chewing | 3 |
| - Resting period | 4 |

## RESULTS

The pH-telemetric results are presented in Figs. 1 to 6 and summarized in Table I where they are compared with the data obtained in November 1996. The pH-values registered following the chewing of neutral paraffin (PC) coincide with those found in earlier tests with the same volunteers and plaque ages. They suggest physiological oral conditions in the test subjects. The pH-decreases occurring subsequently to the 0.3 mol/L (10%) sucrose rinses used as positive control gave evidence of an accurate functioning of the pH-telemetric equipment and of plaque metabolism.

The results in Figs. 1 to 6 clearly show that there was no critical (i.e. below pH 5.7) decrease in the pH of interdental plaque due to bacterial fermentation of Tagatose neither during the rinsing periods nor during the 30 minute periods following the consumption of the tested Tagatose solutions. After the consumption of sucrose (sucrose rinse), plaque-pH always fell well below the critical pH-value (5.7) due to the glycolytic production of bacterial acids.

D-Tagatose has earlier been described as being hypoacidogenic in the oral cavity because it is only very slowly fermented by oral microorganisms[7]. This report shows that plaque layers having grown up under the constant exposure to D-Tagatose were not more acidified by a 10% Tagatose-rinse than non-exposed plaque layers in the same volunteers.

## CONCLUSIONS

The results of this pilot study show that under the chosen conditions of adaptation (3 to 7 days) there was no telemetrically measurable increase of acid production in interdental plaque exposed to D-Tagatose.

Prof. Dr.T.Imfeld, DDS, MBA

Zurich, February 1998
G13/candy-b

## Legends to Figures

Figs. 1 to 6

Telemetrically recorded pH of interdental plaque in different volunteers during and for 30 min after a 2 min rinse of a 10% aqueous solution of D-Tagatose. Two-minute 0.3 mol/L (10%) sucrose rinses were administered as positive controls. (PC) = Paraffin chewing. (id) = age of interdental plaque (i) in days (d).

## LITERATURE


1. Proceedings "Methods of Caries Prediction". Eds. Bibby and Shern. Sp. Supp. Microbiology Abstracts, 1978.

2. Scientific Consensus Conference on Methods for Assessment of the Cariogenic Potential of Foods, San Antonio, Texas, Nov. 17-21, 1985. J Dent Res 65 (Spec Iss), 1473-1543, 1986.

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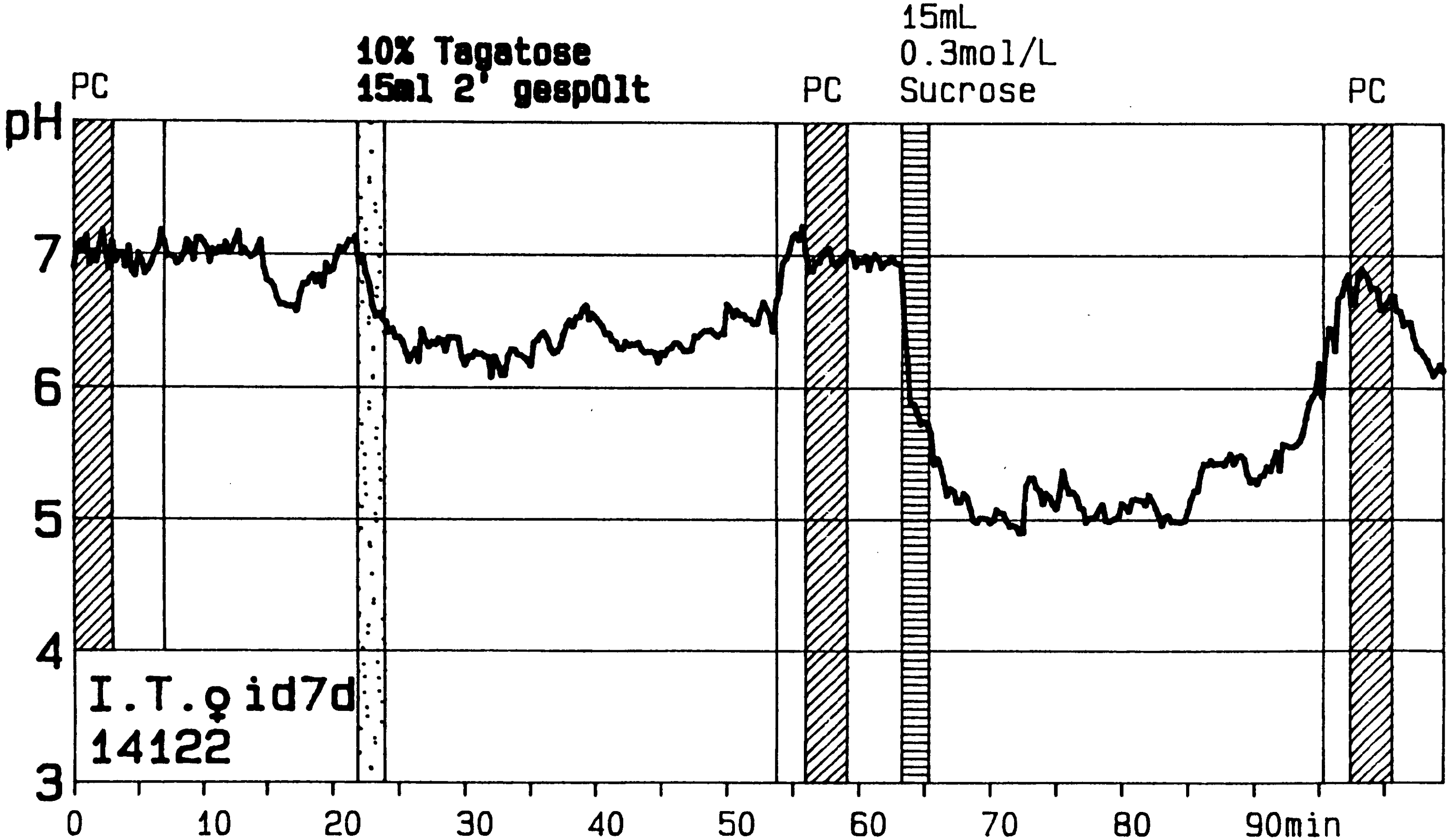
11. Imfeld, T., Lutz, F.: Intraplaque acid formation assessed in vivo in children and young adults. Pediatric Dentistry 2, 87-93, 1980.

Table I

Influence of different test patterns on the telemetrically measured pH of interdental plaque. The pH-values listed are the lowest values found during the respective control periods of the recording sessions.

| Test Pattern | I. | | | | | | I. | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Measurements | 6 | | | | | | 6 | | | | | |
| Figure | 1 | 2 | 3 | 4 | 5 | 6 | 1 | 2 | 3 | 4 | 5 | 6 |
| Age of Plaque (days) | 7 | 3 | 6 | 4 | 5 | 4 | 7 | 3 | 6 | 4 | 5 | 4 |
| pH initial Paraffin | 6.80 | 6.70 | 7.10 | 7.15 | 6.85 | 6.95 | 6.90 | 6.75 | 7.15 | 7.05 | 6.90 | 6.95 |
| pH 10% D-Tagatose | 5.70 | 5.75 | 6.30 | 6.20 | 6.25 | 5.95 | 6.05 | 5.75 | 6.55 | 6.00 | 6.45 | 6.30 |
| pH 0.3 mol/L sucrose | 4.10 | 4.35 | 4.60 | 4.20 | 4.50 | 4.45 | 4.90 | 4.15 | 4.60 | 4.65 | 4.75 | 4.80 |
| pH final Paraffin | 5.35 | 5.80 | 6.60 | 6.00 | 6.60 | 6.15 | 6.70 | 6.35 | 6.60 | 6.50 | 6.90 | 6.55 |
| | Data from report dated November 1996 <u>without</u> adaptation | | | | | | Data from present study <u>with</u> adaptation | | | | | |



PC
10% Tagatose
15ml 2' gespült
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
I.T.♀ id7d
14122
0
10
20
30
40
50
60
70
80
90min


Fig. 1

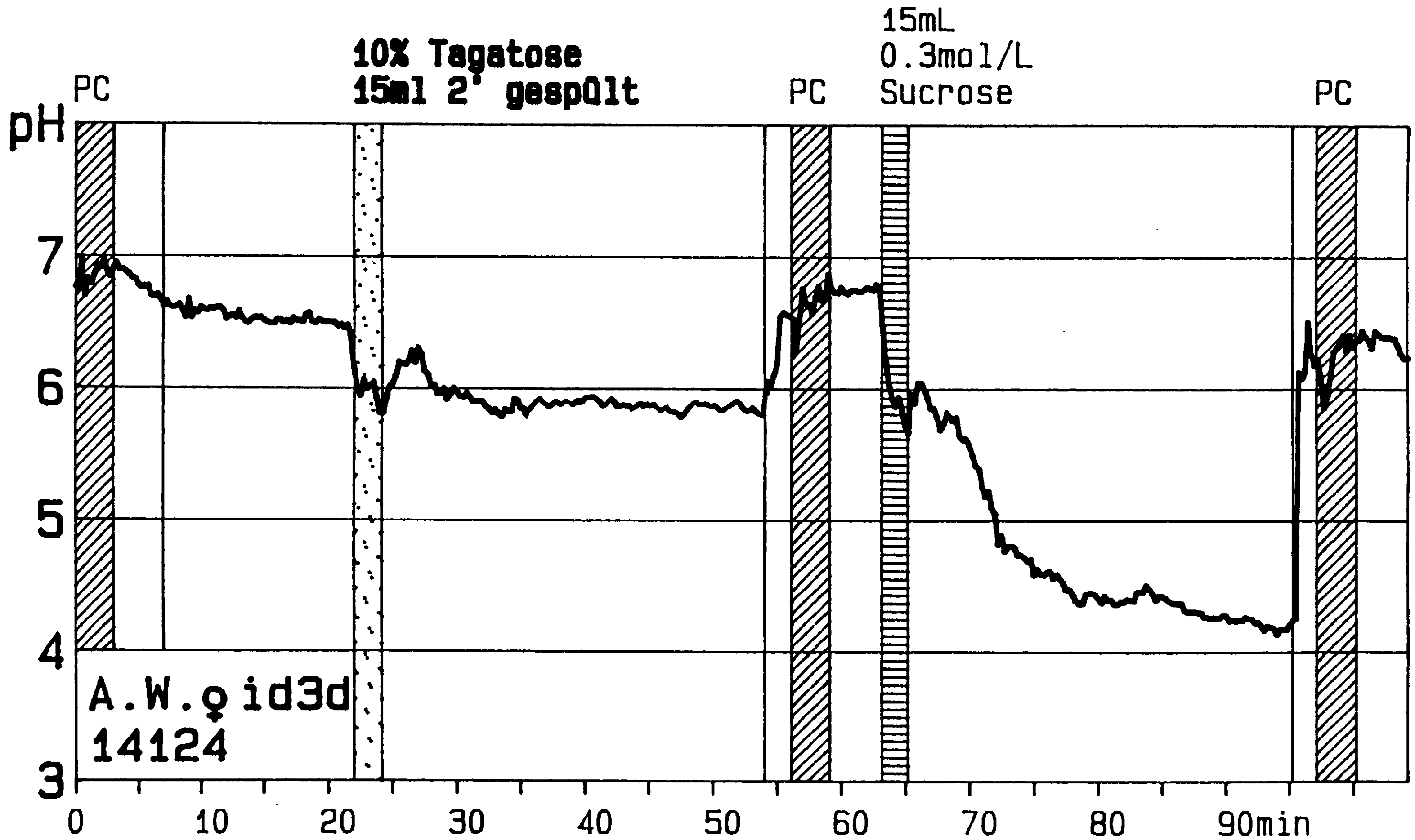
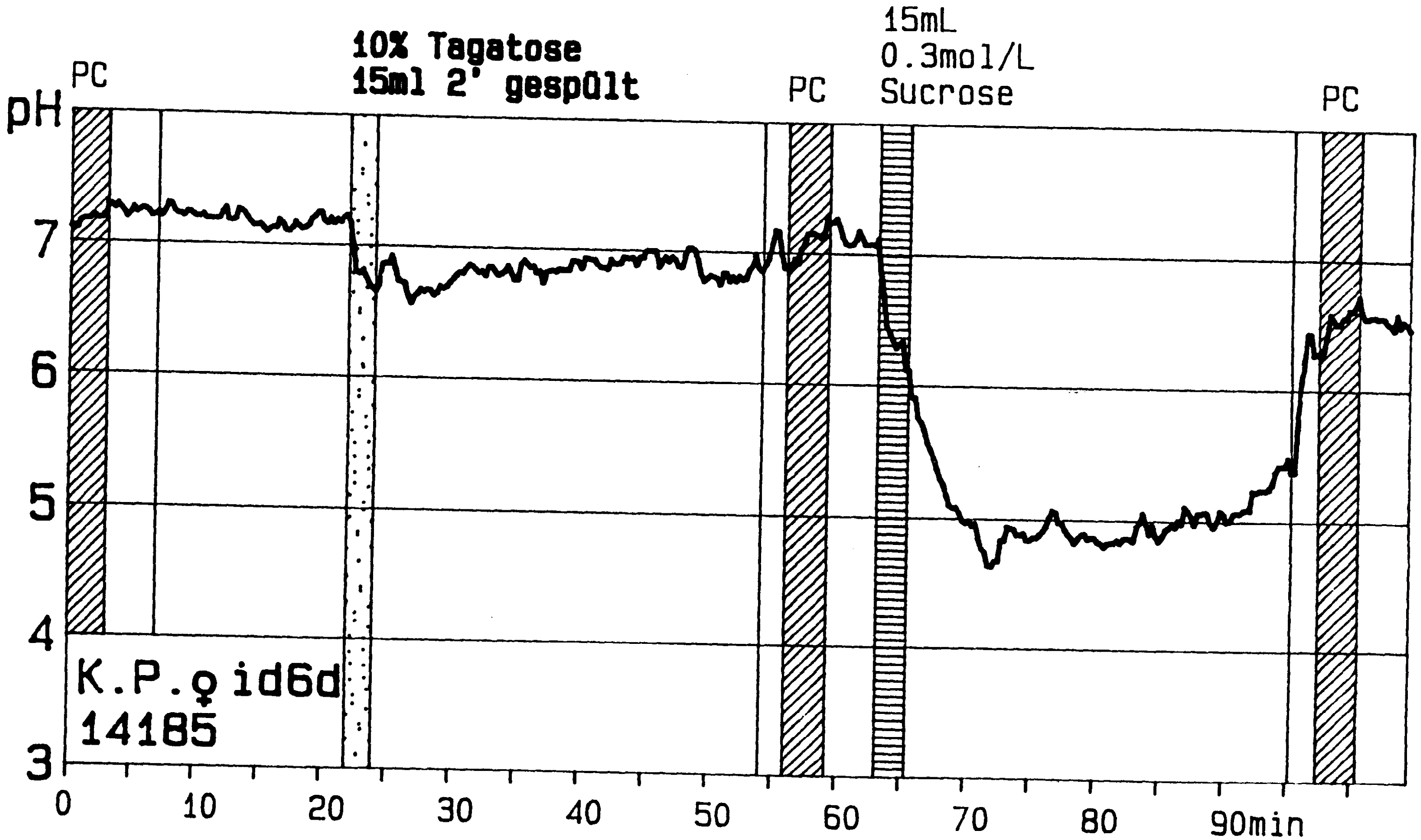

PC
10% Tagatose
15ml 2' gespült
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
A.W.♀ id3d
14124
0
10
20
30
40
50
60
70
80
90min

Fig. 2



PC
10% Tagatose
15ml 2' gespÜlt
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
K.P.♀ id6d
14185
0
10
20
30
40
50
60
70
80
90min


Fig. 3

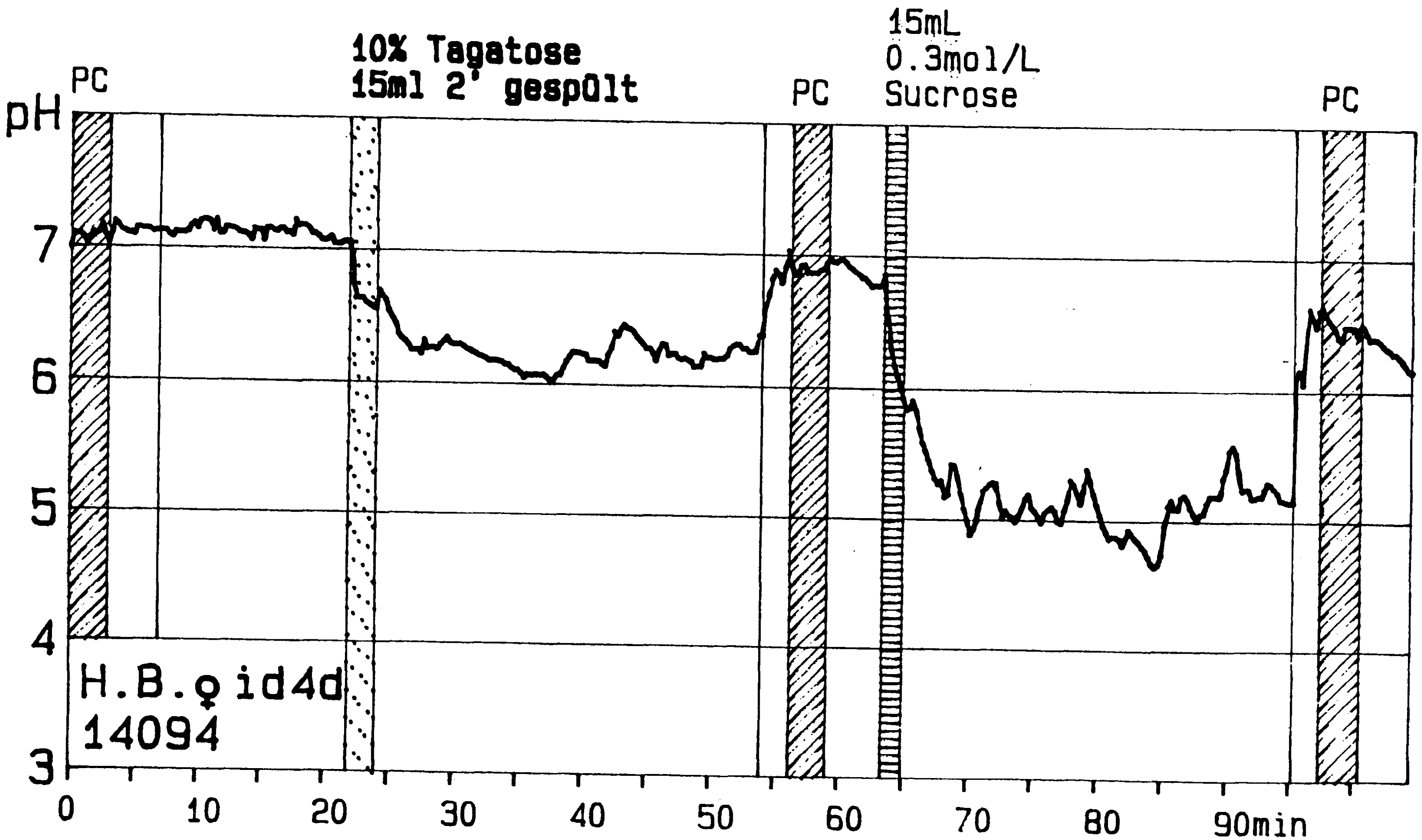

10% Tagatose
15ml 2' gespült
15mL
0.3mol/L
Sucrose
PC
PC
PC
pH
7
6
5
4
3
H.B.♀id4d
14094
0
10
20
30
40
50
60
70
80
90min

Fig. 4

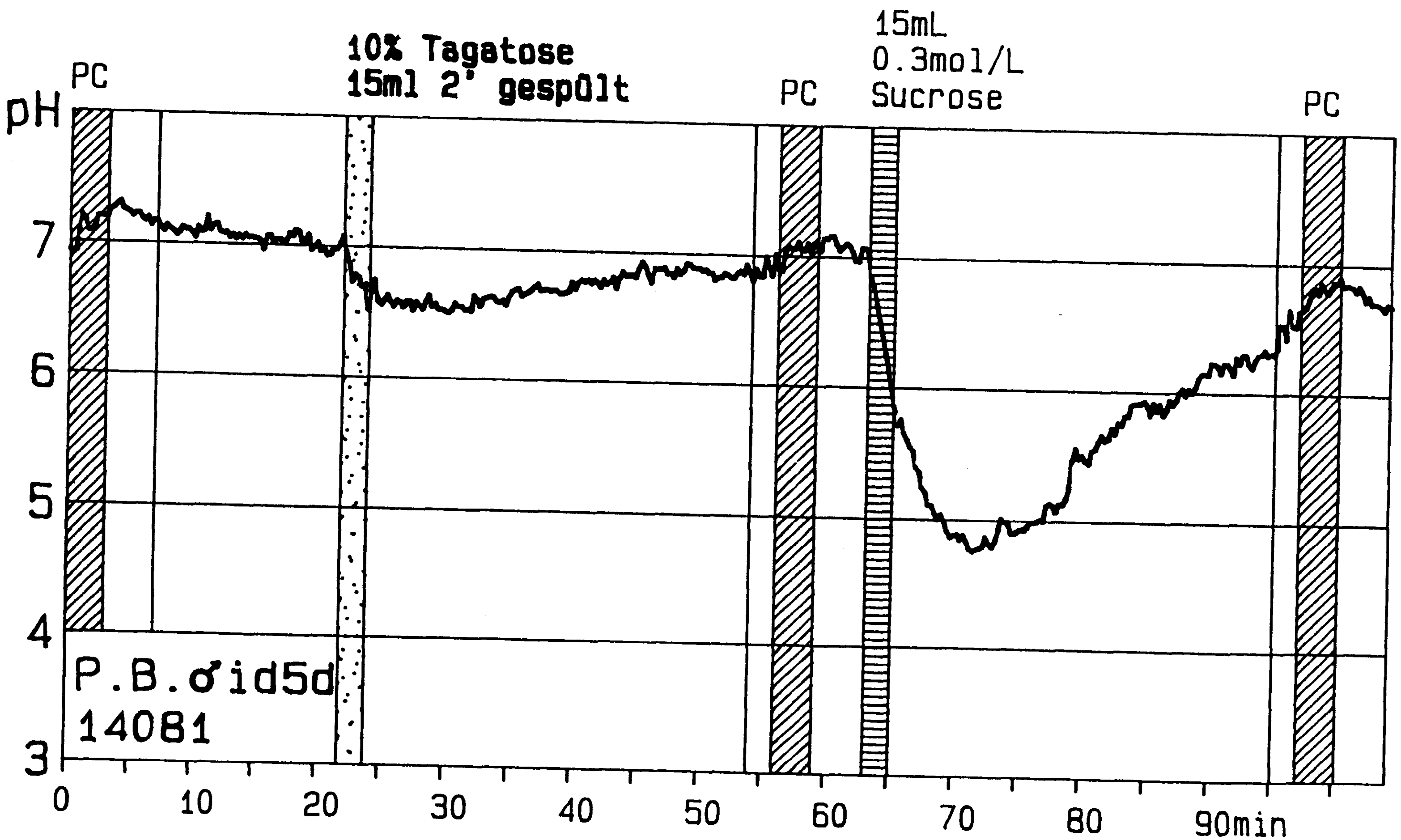

PC
10% Tagatose
15ml 2' gespült
PC
15mL
0.3mol/L
Sucrose
PC
pH
7
6
5
4
3
P.B.♂id5d
14081
0
10
20
30
40
50
60
70
80
90min

Fig. 5

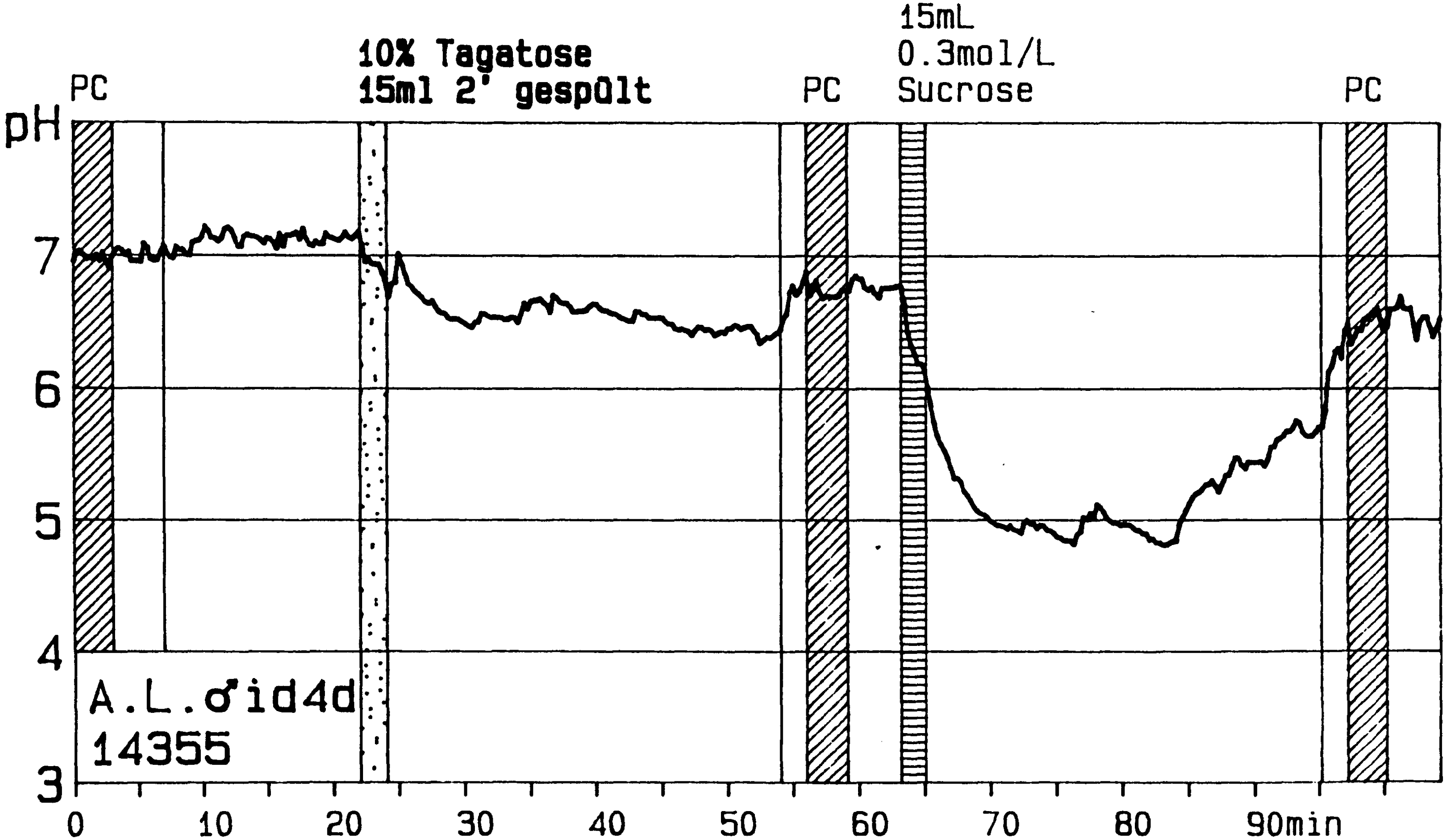

15mL
0.3mol/L
Sucrose
10% Tagatose
15ml 2' gespült
PC
PC
PC
pH
7
6
5
4
3
A.L.♂id4d
14355
0
10
20
30
40
50
60
70
80
90min

Fig. 6